



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																									
Company Name: Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited) Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202437 Medical Device Class, if applicable: <input type="text"/> DUNS: 858949204 Proprietary Name (If Applicable) and Established Name: Folic Acid 1mg 1000ct Selling Unit NDC: 72241-0050-11 Unit of Use NDC: <input type="text"/> UPC: 372241050114 UDI <input type="text"/> CVX Code: <input type="text"/> MX Code: <input type="text"/> Description: Folic Acid 1mg 100ct Tablets Active Ingredient(s): Folic Acid URL for Additional Product Information: www.modavar.com Address: 1016 16th St., NW, Suite 602 Address 2: <input type="text"/> City: Washington State: DC Zip: 20036 Key Contact: Tamara Solomon Email: Tsolomon@modavar.com Phone Number: 202-355-9785 x 4 Fax: 202-355-9784 Product Therapeutic Classification: <input type="text"/>				a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in): <input type="text"/> Notes: <input type="text"/> Is this product to be shipped to customers on ice? <input type="checkbox"/> Is this product to be shipped to customers on dry ice? <input type="checkbox"/> b. Contact for temperature excursion questions: Name: Customer Service Number: 800-688-4697 Group E-mail: ModavarCS@Eversana.com c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> Yes Protect product (unit of sale) from light? <input type="checkbox"/> Yes e. Shelf life: <input type="text"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																									
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION																																									
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # <input type="text"/> a product kit? <input type="checkbox"/> if yes, list NDCs of component parts <input type="text"/> reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> If Unit Dose, indicate NDC here: <input type="text"/>		Is the Product... Is the Product... Direct And Drop-Ship <input type="checkbox"/> Neither <input type="checkbox"/> Orphan Drug Status: <input type="checkbox"/> FDA Approval Status: <input type="text"/> Allergens Present: See Package Insert Country of Origin: India Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		Size: 1000ct Strength: 1MG Dosage Form: Tablets Product Shape: Round, bi-convex Product Color: Yellow Product Imprint: uncoated ,debossed with "C3" on one side and		Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In <input type="text"/> What is the NDC selling unit? <input type="text" value="1 bottle of 100ct tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="text" value="6"/> Each <input type="text"/> Inner/ Carton/Pack <input type="text"/> Case																																							
FOR GENERIC DRUG PRODUCTS				PHARMACY ORDER / BILL UNIT																																									
I. Orange Book Rating: AA <input type="checkbox"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Folvite®				Rec. sell unit to customer? <input type="text" value="1 pill"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION																																									
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Is product exempt from DSCSA? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, attach documentation from FDA. <input type="text"/> GLN: 372241000003 GCP: <input type="text"/> If yes, was original product purchased direct from mfr? <input type="checkbox"/> Provide source manufacturer for repackaged product <input type="text"/>				<table border="1" style="width:100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2">Item/Each:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2">Saleable # Pieces</th> </tr> <tr> <th>Depth</th> <th>Width</th> <th>Height</th> </tr> </thead> <tbody> <tr> <td>Item/Each:</td> <td>0.275</td> <td>2.63</td> <td>2.63</td> <td>4.76</td> <td>32.924444</td> <td>1</td> </tr> <tr> <td>Box/Carton/Bundle/Inner Pack:</td> <td>3.63</td> <td>5.51</td> <td>5.9</td> <td>8.26</td> <td>268.52434</td> <td>6</td> </tr> <tr> <td>Case:</td> <td>14.25</td> <td>12.6</td> <td>7.48</td> <td>17.7</td> <td>1668.1896</td> <td>24</td> </tr> <tr> <td>Pallet:</td> <td>528</td> <td>39.37</td> <td>43.7</td> <td>47.24</td> <td>81274.956</td> <td>840</td> </tr> </tbody> </table>				Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Item/Each:	0.275	2.63	2.63	4.76	32.924444	1	Box/Carton/Bundle/Inner Pack:	3.63	5.51	5.9	8.26	268.52434	6	Case:	14.25	12.6	7.48	17.7	1668.1896	24	Pallet:	528	39.37	43.7	47.24	81274.956	840
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				WHOLESALE USE ONLY:																																									
				Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>																																									

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

Tamara Solomon



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a Folic Acid 1mg 100ct No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS)

- a. UN/Identif
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger See Package Insert
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- No (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

REGULATORY INFORMATION

Is the Product...

- Controlled Substance? No Controlled Substance Code
- Controlled by State(s)? No Listed Chemical (List I or II)
- ARCOS Reportable? No If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments)

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
	<input type="checkbox"/> Oxidizer
	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/>	<input type="checkbox"/> No
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification

EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>
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REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? <input type="checkbox"/> No	#
Website URL: <input type="text"/>	
Med Guide Required <input type="checkbox"/> No	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
Supplier Manages REMS registry exclusively: <input type="checkbox"/> No	Phone: <input type="text"/>
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	DEA #: <input type="text"/>
Site Enrollment Number assigned by Supplier: <input type="text"/>	NCPDP#: <input type="text"/>
	NPI #: <input type="text"/>
Comments <input type="text"/>	
Registry: <input type="checkbox"/>	Phone: <input type="text"/>
Comments <input type="text"/>	

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 800-688-4697	
Is product returnable for credit: <input type="checkbox"/> Yes	
URL/Link to returns policy: ModavarCS@Eversana.com	
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/>	
If so, which states? Other requirements? Comments? <input type="text"/>	



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / c Folic Acid 1mg Name: <input type="text"/></p> <p>Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/></p> <p>Fax: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Additional Notes:	Folvite®
<p><input type="text"/></p>	<p><input type="text"/></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>